

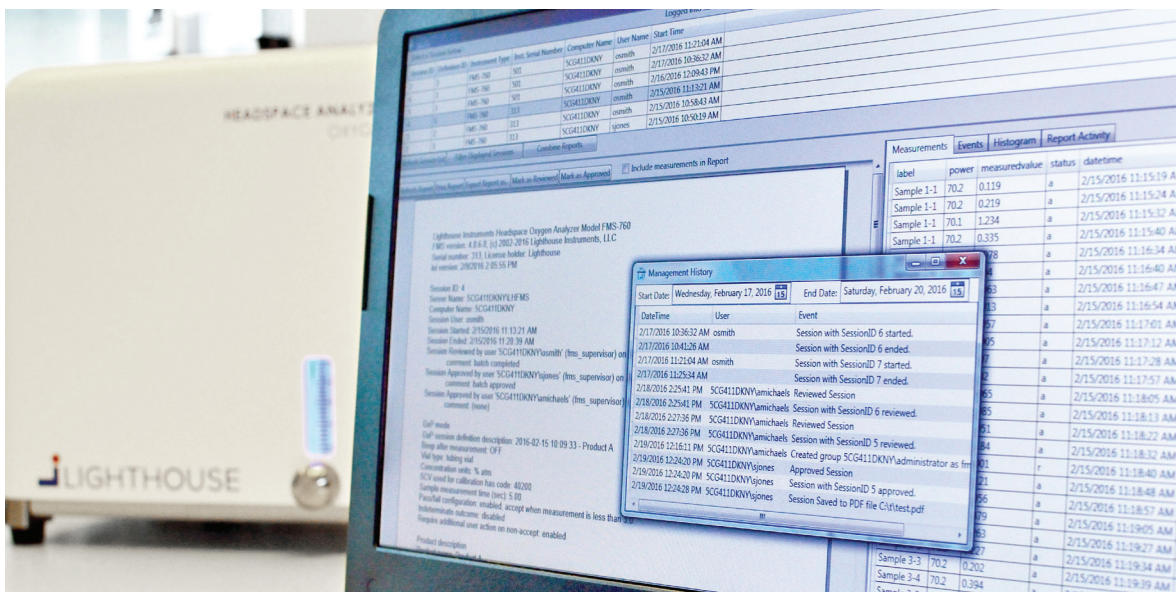
FMS GxP Database Software

PRODUCT DESCRIPTION

The FMS GxP Database software package brings enhanced compliance features and centralized data management to the FMS family of non-destructive headspace analyzers. Data collected with the FMS GxP Database software is stored in a secure database and accessed from any networked computer through the included FMS Database Viewer software, which incorporates new tools to filter, review, approve, print or export data from a single user interface. With password-protected user access and a full audit trail, the FMS GxP Database software represents a comprehensive solution to address the current data integrity concerns of the industry.

Main features:

- Password-protected software access with multi-tiered user privileges
- Data stored in the secure database can not be modified or deleted
- Results logged to the database at the time of measurement
- Stand-alone database viewer provides access to raw data and batch reports
- Searchable database allows for easy retrieval of measurement data or user events
- Electronic signatures for review & approval
- Includes a complete system audit trail with time & date stamp and user attribution.





All FMS analyzers are provided with the basic software package, which includes the following software modes: FMS Open, FMS GxP Print, and FMS GxP File. The FMS GxP Database software package is available as a software add-on for new or existing FMS systems when additional data management features are required. A comparison of the complete set of features for each software mode is presented in the table below.

● <i>natively supported</i>	○ <i>requires external controls and/or policies</i>				
FEATURES DESCRIPTION	FMS OPEN	FMS GxP PRINT	FMS GxP FILE	FMS GxP DATABASE	
Password-protected user access		○	○	●	
Support for Windows Active Directory				●	
Multi-tiered access to functions based on user group				●	
User-generated measurement method definitions		●	●	●	
User-defined pass/fail configuration	●	●	●	●	
Enforced sequence of calibration and verification		●	●	●	
Minimal operator training required	●	●	●	●	
Measurements presented in human-readable form	●	●	●	●	
Data stored as electronic record	●		●	●	
Data stored at the time of measurement		●		●	
Time/date stamp of measurements and events	●	●	●	●	
Data cannot be overwritten	●	●	●	●	
Restricted data storage location			●	●	
Data protected from modification		○	○	●	
Secure data viewer software				●	
Data accessible on local network	●		●	●	
Electronic signatures for review & approval				●	
Searchable database of measurement sessions				●	
Export data to Excel	●		●	●	
Export data to PDF				●	
Audit trail of measurement activity		●	●	●	
Audit trail of all system activity				●	
Full validation package available	●	●	●	●	
Compliant with Title 21 CFR Part 11		○	○	●	

